IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF UTAH

SOLOMON ABADY, et al., Plaintiffs, vs. LIPOCINE INC., et al., Defendants.	**MEMORANDUM DECISION AND ORDER GRANTING MOTION TO DISMISS** Case No. 2:19-cv-00906 Judge Clark Waddoups

Before the court is Defendants' motion to dismiss Plaintiffs' amended complaint, pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, for failure to state a claim for relief in compliance with the pleading requirements set forth in Rules 8 and 9(b) of the Federal Rules of Civil Procedure and the Private Securities Litigation Reform Act of 1995, 15 U.S.C. § 78u-4(b) ("PSLRA"). (ECF No. 47.) The court heard oral argument on Defendants' motion on January 12, 2022. After considering the parties' briefing and arguments, the court now grants Defendants' motion for the reasons set forth herein.

Background

Founded in 1997, Lipocine is a biopharmaceutical company headquartered in Salt Lake City, Utah that focuses on the development of pharmaceutical treatment options relating to men's and women's health. (Am. Compl. at ¶¶, 2 & 30, ECF. No. 44.) Lipocine primarily focuses on the development of oral delivery solutions for poorly bioavailable drugs. (*Id*. at ¶ 30.)

Lipocine's lead product candidate is TLANDO (LPCN 1021), an oral testosterone replacement therapy. (*Id*. at ¶ 31.) TLANDO is an oral capsule containing testosterone undecanoate (TU) in a lipid formulation. (*Id*. at ¶ 33.) TLANDO is designed to enable absorption of TU by the intestines, where it can then be converted into testosterone by the body. (*Id*.) TLANDO is intended to function as an oral testosterone replacement therapy ("TRT") for adult males whose bodies do not produce sufficient levels of testosterone, a condition known as hypogonadism. (*Id*.)

On August 31, 2015, Lipocine submitted its initial New Drug Application ("NDA") for TLANDO to the United States Food and Drug Administration ("FDA"), seeking approval of the drug for marketing in the United States. (*Id*. at ¶ 36.) Lipocine's initial application for TLANDO was based on its Phase 3 clinical Study of Oral Androgen Replacement ("SOAR" or "Study 13-001"), which evaluated the efficacy and safety of TLANDO. (*Id*.)

In June 2016, Lipocine received a Complete Response Letter ("CRL")[1] from the FDA indicating that its initial NDA for TLANDO could not be approved in its current form because the dosing regime in Lipocine's SOAR study differed significantly from the dosing regimen proposed in the 2015 NDA. (*Id*. at ¶ 37.) After being informed that its initial application for TLANDO would not be approved, Lipocine met with the FDA in a Post Action Meeting where it was told by the FDA that the proposed dosing regime for TLANDO would need to be validated through additional clinical trials before a new application for TLANDO could be resubmitted. (*Id*. at ¶ 38.)

[1] A CRL is a communication from the FDA to an applicant indicating that a drug application cannot be approved in its current form. (Am. Compl. at ¶ 2 n.1.)

In response to the FDA's feedback, Lipocine conducted two additional clinical studies of TLANDO: the Dosing Validation Study ("DV Study") and the Dosing Flexibility Study ("DF Study"). (*Id*. at ¶ 39.) In both studies, subjects received 450 mgs of TU per day, but in the DV Study, subjects received the drug in two equally divided doses of 225 mgs of TU, while subjects in the DV Study received the drug in three equally divided doses of 150 mgs of TU. (*Id*. at ¶ 40.)

The purpose of both studies was to (1) evaluate the proper dosing regimen to achieve the desired levels of testosterone in hypogonadal patients and (2) assess whether administering TLANDO would lead to unsafe levels of testosterone in the body. To assess the safety and efficacy of testosterone replacement candidates, the FDA established predetermined metrics against which the results of a clinical trial can be compared. These metrics, referred to as "endpoints," measure the average or maximum level of testosterone in the body after a drug has been administered for a set amount of time.

To evaluate the efficacy of a testosterone replacement product, the FDA established a primary endpoint for the DV and DF Studies that required at least 75% of TLANDO-treated subjects to achieve a 24-hour average serum testosterone concentration within the range of 300-1080 ng/dL upon completion of 24 days of treatment. (*Id*. at ¶ 42.)

To assess the safety of TLANDO, the FDA also established pre-determined secondary endpoints for the DV and DF Studies that set maximum testosterone concentration limits ("Cmax") in patients after 24 days of treatment. (*Id*. at ¶ 43.) To satisfy the FDA's secondary endpoint standards, the DV and DF Studies had to meet the following conditions:

- 85% of subjects with a testosterone Cmax less than or equal to 1,500 ng/dL;
- ≤5% of subjects with a testosterone Cmax between 1,800 and 2,500 ng/dL; and

- No subjects with a testosterone Cmax greater than 2,500 ng/dL.

(*Id*. at ¶ 43.)

On June 19, 2017, Lipocine issued a press release announcing the results of the DV and DF Studies and indicating that it would resubmit its NDA for TLANDO to the FDA in the third quarter of 2017. (*Id*. at ¶ 44; Decl. of Ryan Blair at Ex. I,[2] ECF No. 48-10.) In the June 2017 Press Release, Lipocine indicated that TLANDO met the FDA's primary endpoints in the DV Study, with 81% of subjects achieving average testosterone levels within the predetermined range after treatment. (Decl. of Ryan Blair at Ex. I.)

With respect to the FDA's secondary endpoints standards, the June 2017 Press Release indicated that Lipocine had measured maximum testosterone concentrations in patients using two methodologies: Cmax per dose and Cmax per day. With respect to those measures, the press release stated:

> In the DV study Cmax per dose analysis, the percentage of subjects with Cmax less than 1500 ng/dL and between 1800 ng/dL and 2500 ng/dL were 85% and 7% respectively. Deviations from the predetermined limits in the DV study were observed in the Cmax per day dose analysis for these thresholds. Only one subject, who was a major protocol violator, exceeded the 2500 ng/dL limit independent of per dose or per day dose analyses.
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> The DF study met all Cmax thresholds in per dose and per day dose analyses.

(*Id*.) In August 2017, Lipocine resubmitted its NDA for TLANDO to the FDA based on the results from the DV Study. (*Id*.)

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[2] Exhibit I to the Blair Declaration is a document that Defendants have asked the court to take judicial notice of. As set forth in a separate order issued by the court contemporaneously with this decision, Defendants request that the court take judicial notice of certain documents has been granted-in-part and denied-in-part.

After receiving the resubmitted NDA for TLANDO, the FDA scheduled a meeting of the Bone, Reproductive, and Urologic Drugs Advisory Committee ("BRUDAC")[3] to discuss the pending TLANDO NDA, which was held on January 10, 2018. (Am. Compl. at ¶ 45.) Before the January 2018 BRUDAC meeting, both Lipocine and the FDA prepared briefing materials for consideration by the BRUDAC panel, which were publicly available. (*Id*. at ¶ 46.)

In their BRUDAC briefing materials, both Lipocine and the FDA referenced the secondary endpoint results from the DV Study as measured by the per day method and acknowledged that the DV Study did not meet the predetermined secondary endpoints. (*Id*. at ¶ 46.) The FDA indicated in its BRUDAC briefing that it would seek the advisory committee's input on the relevance of the secondary endpoint findings to the safe use of TLANDO. (Decl. of Ryan Blair at Ex. A, p.5, ECF. No. 48-2.)

Prior to the BRUDAC meeting, on January 5, 2018, Lipocine took out a $10 million loan from Silicon Valley Bank ("SVB Loan"). (*Id*. at ¶ 55.) Under the terms of the loan, which was set to mature on December 1, 2021, Lipocine was required to pay monthly interest until January 1, 2019, after which Lipocine was required to make equal payments of principal and interest for the remainder of the loan. (*Id*. at ¶¶ 55-56.) After the initial interest only payments, Lipocine was required to pay $3.33 million of principal each year until the loan matured. (*Id*. at ¶ 56.) An additional $650,000 final payment was also required at maturity. (*Id*.)

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[3] The BRUDAC was an FDA advisory committee established, under Section 505(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(n)), to provide the FDA with independent expert scientific advice and recommendations regarding a clinical investigation of a drug or the approval of marketing of a drug. While the FDA is required to review the conclusions and recommendations of an advisory committee panel, § 505(n)(7), final decisions regarding the approval of a new drug remain with the FDA.

At the BRUDAC meeting, both Lipocine and the FDA included slides in their presentations that included secondary endpoint data from the DV Study as measured by the per day method. (Am. Compl. at ¶¶ 47-48.) The FDA noted, in its slide presentation, that "the secondary efficacy endpoint was not met for any of the predetermined limits" in the DV Study. (*Id*. at ¶ 48.) In its slide regarding the secondary endpoint results from the DV Study, the FDA noted that one subject that exceeded the maximum threshold for Cmax (i.e., Cmax > 2,500 ng/dL) had a "history of cholecystectomy, which was one of the exclusion criteria." (*Id*.) The slide also noted, however, that it was unclear whether the protocol violation contribute to the Cmax excursion. (*Id*.)

During its presentation to the BRUDAC panel, the FDA again described the secondary endpoint results of the DV Study on a per day basis and indicated that it would ask the committee to "explore this issue in detail over the course of the day." (*Id*. at ¶ 49.)

In its presentation to the BRUDAC panel, Lipocine attempted to justify the Cmax excursions in its DV Study by noting that they were transient and isolated events that were not correlated with adverse effects. (Blair Decl. at Ex. C, p. 36.) It also argued that the FDA's secondary endpoints were primarily developed for products that would provide sustained testosterone at a high level, while the Cmax excursions observed in the DV Study were "a very transient thing." (*Id*. at p. 37.)

During the question-and-answer portion of the BRUDAC meeting, a member of the panel asked the FDA whether it agreed with Lipocine that the Cmax excursions in the DV Study were of very short duration and therefore not of great clinical concern. (Blair Decl. at Ex. C., pp. 38-39.) The FDA indicated that the topic was very novel for the FDA and that it was seeking input from the committee on how to handle the Cmax outliers in the DV Study. (*Id*. at p. 39.) It also

noted that if the same excursions had been found in a topical testosterone product, it would "reject the application and say it shouldn't be approved." (*Id*.) But because topical applications have a different pharmacokinetic profile from TLANDO, it was seeking guidance from the committee. (*Id*.)

After hearing presentations from Lipocine and the FDA, members of the committee discussed several topics relating to TLANDO, including whether TLANDO's failure to meet the FDA's secondary endpoints during the DV Study presented a safety concern. (Blair Decl. at Ex. C, pp. 40-43.) Two members of the BRUDAC panel indicated that they were not concerned about Cmax excursions during the DV Study, noting that the excursions were transient and questioning whether there was any evidence that T levels that exceeded the thresholds set by the FDA were actually dangerous. (*Id*. at 40-42.) One member of the panel indicated that she was concerned about the lack of data regarding the impact of subjects experiencing Cmax peaks twice daily, given TLANDO's twice a day dosing. (*Id*. at 41.) Another panelist noted that there was not a lot of evidence that TLANDO's Cmax excursions had any safety impact but expressed a desire for more data regarding adverse effects that may have been experienced by subjects that had a Cmax that exceeded the FDA's secondary endpoint limits. (*Id*. at 42-43.)

At the conclusion of the meeting, the BRUDAC panel voted 13-6 against recommending approval of TLANDO. (Am. Compl. at ¶ 53.) In explaining their votes, however, only one member identified TLANDO's failure to meet the FDA's secondary endpoint standard in the DV Study as a secondary reason for voting against approval. (Blair Decl. at Ex. C. pp. 44-45.) No other member of the BRUDAC panel identified a concern regarding secondary endpoints as a basis for voting against approval. (*Id*. at pp. 44-63.) Instead, the BRUDAC members were primarily concerned

with the cardiovascular safety of TLANDO and the need for an ambulatory blood pressure study. (*Id*.)

On May 8, 2018, Lipocine received a second CRL from the FDA indicating that the resubmitted TLANDO NDA could not be approved in its current form. (Am. Comp. at ¶ 54.) The May 2018 CRL triggered a condition in Lipocine's SVB Loan that required Lipocine to maintain $5 million of cash collateral with Silicon Valley Bank until TLANDO was approved by the FDA. (*Id*. at ¶ 56.)

According to a press release filed by Lipocine with the SEC, the CRL identified four deficiencies that prevented approval of the TLANDO NDA:

> [1] determining the extent, if any, of *ex vivo* conversion of testosterone undecanoate ("TU") to testosterone ("T") in serum blood collection tubes to confirm the reliability of T data; [2] obtaining definitive evidence pre-approval via an ambulatory blood pressure monitoring study as to whether TLANDO causes a clinically meaningful increase in blood pressure in hypogonadal men; [3] verifying the reliability of Cmax data and providing justification for non-applicability of the agreed-upon and prespecified Cmax secondary endpoints for TLANDO; and [4] determining the appropriate stopping criteria that can reproducibly and accurately identify those patients who should discontinue use of TLANDO.

(*Id*. at ¶ 54 (emphasis omitted).)

In its quarterly report for the quarter ending September 30, 2018, Lipocine disclosed that it had met again with the FDA in a Post Action Meeting to discuss the deficiencies raised in the May 2018 CRL for TLANDO and a path forward for resubmission of a new NDA and potential approval of the drug. (Blair Decl. at Ex. D, p.4.) The report indicated that, during the Post Action Meeting, "[t]he FDA provided specific feedback on potential resolution of each deficiency, including clinical design elements where appropriate." (*Id*.)

The report also announced that Lipocine would conduct new studies to address concerns raised by the FDA with respect to *ex vivo* conversion of TU to T in serum blood collection tubes and potential increases in blood pressure. (*Id*.) With respect to Cmax excursions in the DV Study, the report indicated that Lipocine was "performing additional analyses of existing data in order to address the Cmax deficiency . . . identified by the FDA." (*Id*.) The report also announced that, assuming positive results from the planned studies, Lipocine expected to resubmit an NDA for TLANDO "in the first half of 2019." (*Id*.)

On January 28, 2019, Lipocine filed a Form 8-K with the SEC updating its corporate presentation. (Am. Compl. at ¶ 71.) The corporate presentation included a slide discussing the path forward for resubmission of a TLANDO NDA, which identified Lipocine's plan for addressing deficiencies set out in the May 2018 CRL. (*See id*.; Blaire Decl. at Ex. J, p. 12.) The slide indicated that Lipocine would address concerns regarding Cmax based secondary endpoints through "additional analyses of existing data for resubmission." (*Id*.)

The presentation also included the following slide, that purported to describe TLANDO:

(Am. Compl. at ¶ 72; Blaire Decl. at Ex. J, p. 13.)

Plaintiffs allege that the January 2019 Corporate Presentation included statements that were false and/or misleading because they misrepresented and failed to disclose adverse facts pertaining to the likelihood of the FDA approving TLANDO. (Am. Compl. at ¶ 73.)

In March 2019, the FDA granted approval to Jatenzo, an oral testosterone product that would compete with TLANDO. (Am. Compl. at ¶ 60.)

On May 14, 2019, Lipocine issued a press release announcing that the FDA had accepted a new NDA for TLANDO ("May 2019 TLANDO NDA") and set November 9, 2019 as a goal date for a decision on the application. (*Id*. at ¶ 86.)

Throughout 2019, both before and after Lipocine submitted its May 2019 TLANDO NDA, Lipocine made several other filings with the SEC, including an annual report, quarterly reports, corporate presentations, and press releases, that Plaintiffs allege contained false and/or misleading statements regarding the prospects of TLANDO's approval and the significance of TLANDO's failure to meet the FDA's secondary endpoint thresholds in the DV Study. (Am. Compl. at ¶¶ 74-91.) The court will address the specific statements challenged by Plaintiffs further below.

On September 24, 2019, Defendant Mahesh Patel, Lipocine's President and CEO, gave a presentation at the Ladenburg Thalmann Healthcare Conference regarding the status of TLANDO's application for approval by the FDA. (*Id*. at ¶ 92.) Plaintiffs allege that, during a question-and-answer session, Patel made false and/or misleading statements regarding the prospect of TLANDO's approval and "gave a false impression that the Company had resolved its failure to meet the Cmax secondary endpoints and that the FDA had not raised any concerns about

the Company's failure to address this issue." (*Id*.) The court will also address the specific statements made by Dr. Patel at the healthcare conference further below.

On November 11, 2019, Lipocine announced that it had received another CRL from the FDA rejecting the May 2019 TLANDO NDA. (*Id*. at ¶ 94.) The press release indicated that "[t]he CRL identified one deficiency stating the efficacy trial did not meet the three secondary endpoints for maximal testosterone concentrations ('Cmax')." (*Id*.)[4]

On the same day, Lipocine's stock price fell $1.93 to $0.80 per share, a drop of 70.7%. (*Id*. at ¶ 95.) Lipocine's stock price continued to fall over the following days to close at $0.40 per share on November 14, 2019. (*Id*.)

After news of the FDA's rejection of the May 2019 TLANDO NDA broke, some market analysts predicted that Lipocine would appeal the November 2019 CRL given that they viewed TLANDO's secondary endpoint excursions as similar to, or less significant than, those present in clinical trials of Jatenzo, which had obtained approval several months earlier. (*Id*. at ¶¶ 67-69.) One analyst published a chart comparing Jatenzo's per-day secondary endpoint results to TLANDO's per-dose secondary endpoint measures. (*Id*. at ¶¶ 67-68.) Plaintiffs contend that these analyst reports demonstrate that market analysts were misled by Lipocine regarding the proper measure of TLANDO's secondary endpoints since, according to Plaintiffs', "TLANDO's Cmax results were far worse than Jatenzo's Cmax results under the 'per day' analysis that formed the basis of the predetermined secondary endpoints for Cmax." (*Id*. at ¶ 69.)

[4] TLANDO was ultimately approved by the FDA on March 29, 2022, after this lawsuit was filed. (*See* Notice of Subsequent Development, ECF No. 56.)

Plaintiffs allege that the precipitous fall in Lipocine's stock price following the announcement that the May 2019 TLANDO NDA had been rejected by the FDA was caused by the allegedly false and/or misleading statements challenged in this action. On this basis, Plaintiffs claim that Lipocine's statements constitute securities fraud in violation of Section 10(b) of the Securities Exchange Act and S.E.C. Rule 10b-5. Plaintiffs also assert a claim under Section 20(a) of the Exchange Act against Dr. Patel.

Challenged Statements

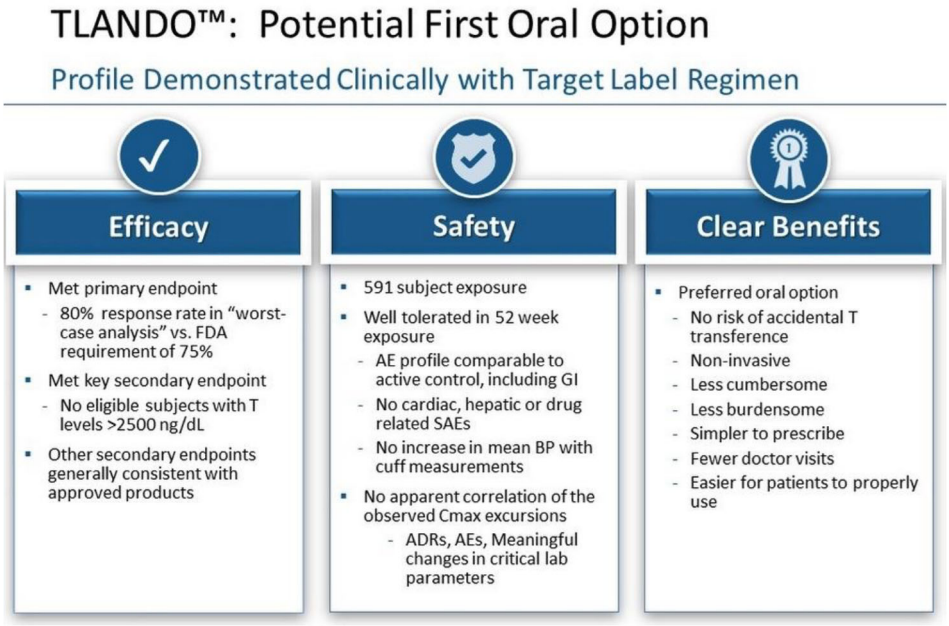
Plaintiffs allege that, between January 28, 2019 and November 11, 2019 (the "Class Period"), Lipocine made nine public statements that included materially false or misleading information about Lipocine's ability to satisfy the FDA's concerns regarding secondary endpoint excursions in the DV Study and TLANDO's overall chances of approval by the FDA.

A. January 2019 Corporate Presentation

On January 28, 2019, Lipocine filed a Form 8-K with the SEC updating its corporate presentation. (Am. Compl. at ¶ 71.) The corporate presentation included a slide discussing the path forward for resubmission of a TLANDO NDA, which identified Lipocine's plan for addressing deficiencies set out in the May 2018 CRL. (*See id.*; Blaire Decl. at Ex. J, p. 12.) The slide indicated that Lipocine would [1][5] "[p]rovide justification for [the] non-applicability of Cmax based secondary endpoints" through "additional analyses of existing data for resubmission." (*Id.*)

[5] With their motion to dismiss, Defendants appended a table identifying the statements that Plaintiffs appear to challenge in their amended complaint, labeling them 1 through 17. (ECF No. 48-1.) In their opposition, Plaintiffs assert that Defendants' appendix is "misleading," but do not explain why the table is misleading or make any effort to more precisely identify what specific statements are challenged by the amended complaint. (ECF No. 50 at 11 n.4.) For ease of reference, the court will refer to each statement apparently challenged by Plaintiffs by the numbers referenced in Defendants' appendix, which are identified herein with brackets.

The presentation also included the following slide, that purported to describe TLANDO:



(Am. Compl. at ¶ 72; Blaire Decl. at Ex. J, p. 13.)

Plaintiffs allege that this slide contains two materially false statements: that TLANDO [2] "[m]et [the] key secondary endpoint" and that [3] "[o]ther secondary endpoints [were] generally consistent with approved products." (Am. Compl. at ¶ 72.)

Plaintiffs further contend, generally, that the January 2019 Corporate Presentation was materially false and/or misleading because it "misrepresented and failed to disclose adverse facts pertaining to the likelihood of the FDA approving the 2019 TLANDO NDA . . . which were known to Defendants or recklessly disregarded by them." (*Id*. at ¶ 73.)

B. Annual and Quarterly Reports

On March 6, 2019, Lipocine filed its 2018 annual report with the SEC. (Am. Compl. at ¶ 74.) Using language that was nearly identical to the September 2018 quarterly report, the 2018

annual report described the deficiencies raised by the FDA in the May 2018 CRL for TLANDO and discussed how Lipocine intended to address those deficiencies. (*Id*. at ¶ 75.) The report stated:

> [4] The CRL identified four deficiencies which include the following: determining the extent, if any, of ex vivo conversion of TU to T in serum blood collection tubes to confirm the reliability of T data; obtaining definitive evidence pre-approval via an ABPM study as to whether TLANDO causes a clinically meaningful increase in blood pressure in hypogonadal men, which is a surrogate marker of predicting cardiovascular outcomes; verifying the reliability of Cmax data and providing justification for non-applicability of the agreed-upon and prespecified Cmax secondary endpoints for TLANDO; and, determining the appropriate stopping criteria that can reproducibly and accurately identify those patients who should discontinue use of TLANDO. . . .
>
> [5] On July 19, 2018, we completed a Post Action Meeting with the FDA in which the deficiencies raised in the CRL were discussed and a path forward for NDA resubmission for the potential approval of TLANDO was clarified. The FDA provided specific feedback on potential resolution of each deficiency, including clinical design elements where appropriate. . . . Finally, we are performing additional analyses of existing data in order to address the Cmax deficiency and dose stopping criteria deficiency identified by the FDA. Although there is no guarantee that TLANDO will ever be approved by the FDA, ***we believe the data analyses we are performing together with the results from the definitive phlebotomy study and the on-going ABPM clinical study should address the deficiencies identified by the FDA in its CRL.*** [6] ***Assuming results from the APBM clinical study support resubmission of the TLANDO NDA, we expect resubmission to occur mid-2019 followed by a six-month review by the FDA upon FDA acceptance***. There can be no assurances as to the timing or acceptance of our NDA by the FDA.

(*Id*. (emphasis in Am. Compl.).)

The 2018 annual report also included the following discussion regarding Cmax secondary endpoint data from the DV and DF Studies:

> [7] The secondary endpoints assessed the maximum total testosterone concentration ("Cmax") post dosing using

> predetermined limits developed by the FDA for transdermals. The FDA guidelines for secondary efficacy success is that at least 85% of the subjects achieve Cmax less than 1500 ng/dL; no greater than 5% of the subjects have Cmax between 1800 ng/dl and 2500 ng/dL; and zero percent of the subjects have Cmax greater than 2500 ng/dL. [8] Consistent with the definition of Cmax and the pharmacokinetic profile of multiple times a day dosing, two prespecified analyses were performed, Cmax per dose and Cmax per day.
>
> [9] ***In the DV study SS Cmax per dose analysis, the percentage of subjects with Cmax less than 1500 ng/dL and between 1800 ng/dL and 2500 ng/dL were 85% and 7%, respectively.*** [10] ***Deviations from the predetermined limits in the DV study were observed in the Cmax per day dose analysis for these thresholds.*** [11] ***Only one subject, who was a major protocol violator, exceeded the 2500 ng/dL limit independent of per dose or per day dose analyses.***
>
> [12] ***The DF study SS met all Cmax thresholds in per dose and per day dose analyses.***

(*Id*. at ¶ 76 (emphasis in Am. Compl.).)

Nearly identical statements were included in Lipocine's quarterly reports for the first and second quarters of 2019. (*Id*. at ¶¶ 84, 90.)

Plaintiffs generally allege that Lipocine's statements regarding the TLANDO's secondary endpoints in the DV and DF Studies, that appeared in Lipocine's annual and quarterly SEC reports during the class period, were materially false and/or misleading because they "misrepresented and failed to disclose adverse facts pertaining to the likelihood of the FDA approving the 2019 TLANDO NDA . . . which were known to Defendants or recklessly disregarded by them." (*Id*. at ¶¶ 77, 87, 91.)

C. March 27, 2019 Press Release

On March 27, 2019, Lipocine issued a press release announcing the results of its ambulatory blood pressure monitoring ("ABPM") clinical study. (*Id*. at ¶ 78.) The press release included the following quotation from Dr. Patel:

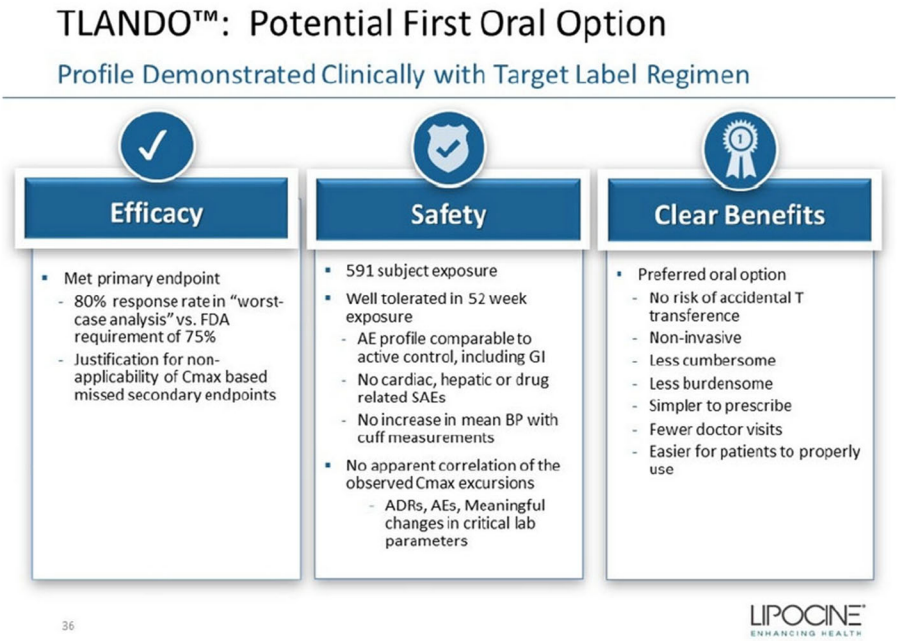
> [13] "We are pleased with the TLANDO pressor results which we believe are in line with a recently approved testosterone replacement therapy. We look forward to resubmitting our NDA in the second quarter of 2019," said Dr. Mahesh Patel, Chairman, President and Chief Executive Officer of Lipocine. Dr. Patel further stated, "We remain committed on bringing our patient-friendly oral testosterone product candidate to patients in timely manner."

(*Id*. at ¶ 78.)

Plaintiffs contend that this statement in the March 27, 2019 press release was materially false and/or misleading because it "misrepresented and failed to disclose adverse facts pertaining to the likelihood of the FDA approving the 2019 TLANDO NDA . . . which were known to Defendants or recklessly disregarded by them." (*Id*. at ¶ 79.)

D. May 2019 Corporate Presentation

On May 1, 2019, Lipocine filed an updated corporate presentation with the SEC. (*Id*. at ¶ 80.) The May 2019 corporate presentation updated the slide describing TLANDO's endpoints as follows: [14]



(*Id*. at ¶ 80.)

Plaintiffs allege that this slide "gave a false impression that the Company had clinically demonstrated a '[j]ustification for non-applicability of Cmax based missed secondary endpoints.'" (*Id*. at ¶ 80.) Plaintiffs further allege, generally, that the updated slide was materially false and/or misleading because it "misrepresented and failed to disclose adverse facts pertaining to the likelihood of the FDA approving the 2019 TLANDO NDA . . . which were known to Defendants or recklessly disregarded by them." (*Id*. at ¶ 81.)

E. May 8, 2019 Press Release

On May 8, 2019, Lipocine issued a press release announcing its financial results for the first quarter of 2019. (*Id*. at ¶ 85.) Included in the press release was a quote from Dr. Patel stating:

> [15] "With the successful completion of the ABPM study for TLANDO, we look forward to resubmitting our NDA for TLANDO in May 2019."

(*Id*. at ¶ 85.)

Plaintiffs allege, generally, that the May 8, 2019 press release was materially false and/or misleading because it "misrepresented and failed to disclose adverse facts pertaining to the likelihood of the FDA approving the 2019 TLANDO NDA . . . which were known to Defendants or recklessly disregarded by them." (*Id*. at ¶ 87.)

F. May 14, 2019 Press Release

On May 14, 2019, Lipocine issues another press release announcing that the FDA had accepted its resubmitted NDA for TLANDO and had set a target date of November 9, 2019 for potential approval. (*Id*. at ¶ 86.) The press release included the following statement regarding the NDA's attempt to address deficiencies identified in the May 2018 CRL:

> [16] The NDA incorporates data compiled by Lipocine in order to address deficiencies identified by the FDA in a Complete Response Letter ("CRL") to the Company in 2018 and discussed in the Post Action Meeting with the FDA.

(*Id*.)

Plaintiffs allege, generally, that this statement "gave a false impression that the Company had resolved its failure to meet the secondary endpoints for Cmax." (*Id*.) Plaintiffs further allege that the May 14, 2019 press release was materially false and/or misleading because it "misrepresented and failed to disclose adverse facts pertaining to the likelihood of the FDA approving the 2019 TLANDO NDA . . . which were known to Defendants or recklessly disregarded by them." (*Id*. at ¶ 87.)

G. September 2019 Conference Presentation

On September 24, 2019, Dr. Patel gave a presentation at the Ladenburg Thalmann Healthcare Conference. (*Id*. at ¶ 92.) During his presentation, Dr. Patel made the following statement regarding the prospects of TLANDO being approved by the FDA:

> [17] Yes, I would characterize as a [inaudible] with FDA today. There's nothing abnormal. It's probably to be normal. There have been some information requests, but I would say nothing too concerning. We had four deficiencies that were identified in the last CRL. We think we were able to ask all four of them, adequately. Of course, we'll have to wait and see even the actual, the PDUFA date, we got approval or not. Historically, we have had a couple of rounds and some surprises. So we're optimistically – I should say cautiously optimistic about – might hopeful of approval in light of seeing that FDA has recently approved two products some few injections as well as an oral product triclabendazole earlier this year.

(*Id*.)

Plaintiffs allege that Dr. Patel's statement "gave a false impression that the Company had resolved its failure to meet the Cmax secondary endpoints and that the FDA had not raised any concerns about the Company's failure to address this issue." (*Id*.) Plaintiffs further allege, generally, that Dr. Patel's statements at the September 2019 conference were materially false and/or misleading because they "misrepresented and failed to disclose adverse facts pertaining to the likelihood of the FDA approving the 2019 TLANDO NDA . . . which were known to Defendants or recklessly disregarded by them." (*Id*. at ¶ 91.)

Legal Standards

Rule 12(b)(6) of the Federal Rules of Civil Procedure permits a defendant to seek dismissal of a claim when a complaint fails to "state a claim upon which relief can be granted." When considering whether dismissal is appropriate under Rule 12(b)(6), the court must "accept as true all well-pleaded factual allegation in the complaint and view them in the light most favorable to the plaintiff." *Burnett v. Mortg. Elec. Registration Sys., Inc.*, 706 F.3d 1231, 1235 (10th Cir. 2013) (citation omitted). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face." *Aschroft v. Iqbal*,

556 U.S. 662, 678 (2009) (citation omitted). The complaint's allegations must allege more than labels or legal conclusions and its factual allegations "must be enough to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

When considering a motion to dismiss for failure to state a claim, the court must also consider the pleading standard that the plaintiff must meet to state a claim for relief. Rule 8(a) of the Federal Rules of Civil Procedure requires that all complaints filed in federal court state a claim for relief that contains "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Thus, a complaint that fails to allege facts that are sufficient to satisfy each element of an asserted claim fails to satisfy Rule 8(a)'s requirements and is subject to dismissal under Rule 12(b)(6).

In cases asserting securities fraud, such as this one, plaintiffs are required to satisfy two additional, heightened, pleading requirements.

First, because securities fraud allegations necessarily require that a plaintiff allege fraud or mistake, such claims are subject to Rule 9(b)'s requirement that a plaintiff state "with particularity the circumstances constituting fraud or mistake." *See Grossman v. Novell, Inc.*, 120 F.3d 1112, 1124 (10th Cir. 1997). Rule 9(b), thus, requires that "to state a claim for securities fraud, 'the plaintiff must set forth what is false or misleading about a statement, and why it is false.'" *Id*. (citation omitted). "In other words, the plaintiff must set forth an explanation as to why the statement or omission complained of was false or misleading." *Id*.

Second, the Private Securities Litigation Reform Act ("PSLRA") opposes additional, heightened, pleading requirements on plaintiffs asserting claim for securities fraud. The PSLRA requires that when a complaint alleges that a defendant made a false or misleading statement or

omission under Section 10(b) of the Securities Exchange Act of 1934 (the "Act"), the complaint "shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). The PSLRA also imposes a heightened pleading standard for allegations that a defendant's false or misleading statements or omissions were made with the requisite scienter, requiring that "the complaint shall, with respect to each act or omission alleged to violate [Section 10(b)], state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2).

Thus, a complaint asserting securities fraud that does not meet the heightened pleading requirements set forth in Rule 9(b) and the PSLRA is also subject to dismissal under Rule 12(b)(6).

Discussion

I. Section 10(b) Claim

Defendants first seek dismissal of Plaintiffs' claim that Defendants made false and misleading statements or omissions in violation of Section 10(b) of the Securities Exchange Act of 1934 and its implementing regulation, S.E.C. Rule 10b-5.

Section 10(b) prohibits any person, "directly or indirectly, by the use of any means or instrumentality of interstate commerce or of the mail, or of any facility of any national securities exchange" from using or employing "in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules or regulations as the [Securities Exchange] Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors." 15 U.S.C. § 78j(b).

To implement Section 10(b), the S.E.C. has adopted Rule 10b-5, which states, in relevant part, that "[i]t shall be unlawful for any person . . . [t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading . . . in connection with the purchase or sale of any security." 17 C.F.R. § 240.10b-5(b).

To state a valid claim under Section 10(b) and Rule 10b-5, a plaintiff must sufficiently allege facts showing that "(1) the defendant made an untrue or misleading statement of material fact, or failed to state a material fact necessary to make statements not misleading; (2) the statement complained of was made in connection with the purchase or sale of securities; (3) the defendant acted with scienter, that is, with intent to defraud or recklessness; (4) the plaintiff relied on the misleading statements; and (5) the plaintiff suffered damages as a result of his reliance." *In re Zagg, Inc. Sec. Litig.*, 797 F.3d 1194, 1200 (10th Cir. 2015) (emphasis and citations omitted).

Defendants challenge the adequacy of Plaintiffs' allegations regarding the first, third, and fifth elements of their Section 10(b) claim, arguing that the complaint fails to adequately allege (1) that Defendants made any false or misleading statements, (2) that Defendants acted with the requisite scienter, and (3) that Defendants' alleged conduct caused the losses alleged by Plaintiffs. Defendants also contend that Plaintiffs' amended complaint constitutes an improper "puzzle pleading" that fails to comply with necessary pleading requirements. The court will address each argument in turn.

A. Puzzle Pleading

As an initial matter, Defendants argue that the amended complaint should be dismissed in its entirety because it is an improper "puzzle pleading" that fails to comply with the pleading

requirements of the Federal Rules of Civil Procedure and the heightened pleading standard set forth in the PSLRA. The court agrees.

Rule 8 of the Federal Rules of Civil Procedure requires that a complaint include a "short and plain statement of the claim showing that the pleader is entitled to relief" based on factual allegations that are "simple, concise, and direct." Fed. R. Civ. P. 8(a)(2) and (d)(1). While, as discussed above, Rule 9(b) and the PSLRA heighten the pleading standard with respect to certain elements in a securities fraud case, they do not relieve a plaintiff of Rule 8's instructions.

Plaintiffs' amended complaint closely resembles a form of pleading that appears to have been pervasive in the context of securities class actions and which courts, including this one, have repeatedly condemned. *See*, *e.g.*, *Boca Raton Firefighters & Police Pension Fund v. Bahash*, 506 F. App'x 32, 37-38 (2d Cir. 2012); *Rumbaugh v. USANA Health Sciences, Inc.*, Case No. 2:17-CV-106, 2018 WL 5044240 at *4 (D. Utah Oct. 17, 2018) (unpublished); *Oklahoma Police Pension & Ret. Sys. v. Boulder Brands, Inc.*, Case No. 15-CV-00679-MSK-KMT, 2017 WL 1148689 at *3–4 (D. Colo. Mar. 28, 2017) (unpublished); *Constr. Workers Pension Fund-Lake Cnty. & Vicinity v. Navistar Int'l Corp.*, Case No. 13 C 2111, 2014 WL 3610877 at *5 (N.D. Ill. July 22, 2014) (unpublished). The pattern is characterized by a tendency to "excerpt long passages including numerous statements and, to a large degree, leave the Court to the task of teasing out which specific statements are at issue." *In re Level 3 Commcs, Inc. Sec. Litig.*, 667 F.3d 1331, 1339 n.8 (10th Cir. 2012) (citation and internal alterations omitted). Such complaints are also characterized by repetitive paragraphs asserting boilerplate reasons why the referenced statements were false or misleading, without any basis for connecting the purported reasons to any particular statement. *See Rumbaugh*, 2018 WL 5044240 at *4.

An example from Plaintiffs' amended complaint illustrates the deficiencies with this approach and the near impossible task it places on Defendants and the court to decipher the basis for Plaintiffs' claim. Paragraph 92 of the amended complaint quotes an exchange held between Dr. Patel and an analyst at a presentation held at the Ladenburg Thalmann Healthcare Conference on September 24, 2019:

> **Matthew Kaplan, Analyst, Ladenburg Thalmann**
>
> Thanks. I think we have time maybe for a couple of questions. Just starting off, obviously, as you said that, you have PDUFA date middle of November – November 9. Can you give us a sense in terms of how your interaction has been with the FDA kind of going into the last month here, roughly, and what your sense is given, it seems as though you addressed the four issues that you had in the CRL previously and most outstanding the ambulatory blood pressure study, which was lacking.
>
> **Mahesh V. Patel, Chairman, President and Chief Executive Officer**
>
> Yes, I would characterize as a [inaudible] with FDA today. There's nothing abnormal. It's probably to be normal. There have been some information requests, but I would say nothing too concerning. We had four deficiencies that were identified in the last CRL. We think we were able to ask [sic] all four of them, adequately. Of course, we'll have to wait and see even the actual, the PDUFA date, we got approval or not. Historically, we have had a couple of rounds and some surprises. So we're optimistically – I should say cautiously optimistic about – might hopeful of approval in light of seeing that FDA has recently approved two products some few injections as well as an oral product triclabendazole earlier this year.

(Am. Compl. at ¶ 92.)

In the following paragraph, Plaintiffs repeat a boilerplate list of purported reasons why the statements in paragraph 92 are allegedly false or misleading:

> The statements referenced in ¶ 92 above were materially false and/or misleading because they misrepresented and failed to disclose

> adverse facts pertaining to the likelihood of the FDA approving the 2019 TLANDO NDA, and which were known to Defendants or recklessly disregarded by them. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) the pre-determined secondary endpoints for Cmax were based on the "per day" analysis, not the "per dose" analysis; (2) only 74% of subjects were below Cmax 1500 ng/dL compared to the >85% target, and 14% of subjects were between Cmax 1800 and 2500 ng/dL compared to the <5% target; (3) the FDA had never approved a comparable testosterone product that deviated so significantly from the predetermined secondary endpoints; (4) the FDA had already concluded that it was unclear whether the protocol violation contributed to the Cmax excursion for the subject who exceeded the 2500 ng/dL limit; (5) the DF Study meeting the secondary endpoints for Cmax was irrelevant to the FDA's consideration of the TLANDO NDA; (6) consequently, the FDA was exceedingly unlikely to approve the TLANDO NDA given that the Company had failed to address the failure to meet the secondary endpoints; and (7) due to the foregoing, Defendants' public statements were materially false and/or misleading at all relevant times.

(Am. Compl. at ¶ 93.) The alleged list of reasons stated in paragraph 93 of the amended complaint is a verbatim repetition of reasons given with respect to other statements that appear in paragraphs 73, 77, 79, 7, 87, and 91 of the amended complaint.

There is nothing in the amended complaint that identifies what portion of the quoted passage in paragraph 92 is alleged to be false or misleading. And there is nothing in the amended complaint that would allow Defendants or the court to decipher which of the boilerplate reasons listed in paragraph 93 show that any or all of the statements quoted in paragraph 92 are false or misleading, despite the fact that many of the purported reasons appear to have nothing to do with the statements in paragraph 92.

Moreover, and significantly, none of the purported reasons listed in paragraph 93 actually explain the reason or reasons why any portion of the statements in paragraph 92 is false or misleading. Instead, paragraph 93 merely lists a set of purported facts that, if disclosed, would

allegedly make the statements in paragraph 92 not misleading. But those facts do not elucidate why the statements in paragraph 92 are misleading in the first instance. This does not satisfy the PSLRA's requirement that a plaintiff "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1).

Plaintiffs' "puzzle-style" complaint places "the burden on the reader to sort out the statements and match them with the corresponding adverse facts to solve the 'puzzle' of interpreting plaintiffs' claims." *Rumbaugh*, 2018 WL 5044240 at *4 (quoting *Primo v. Pacivil Biosciences of Calif., Inc.*, 940 F. Supp. 2d 1105, 1111-12 (N.D. Cal. 2013)). It places an "unwelcome and wholly unnecessary strain on defendants and the court." *Rumbaugh*, 2012 WL 5044240 at *4 (citation omitted).

Accordingly, the court concludes that the amended complaint generally fails to comply with the pleading requirements of Rule 8 and the PSLRA. This is sufficient, by itself, to warrant dismissal. Nevertheless, because the court adheres to the preference for deciding cases on their merits, the court has done its best to decipher the allegations of the complaint to determine whether they provide any support for a viable claim for relief. For the reasons set forth below, the court concludes that they do not and dismisses this action on its merits as well.

B. False and Misleading Statements and Omissions

In their opposition, Plaintiffs argue that the amended complaint alleges that Defendants made two affirmative false or misleading statements and failed to disclose five purportedly material facts relating to the prospect of TLANDO's approval. For the reasons outlined below, none of the statements or omissions identified by Plaintiffs provide a basis for liability under Section 10(b).

1. Affirmative Statements

i. *TLANDO Met the Key Secondary Endpoint. (Statement No. 2)*

Plaintiffs contend that Lipocine made a false and/or misleading statement when it stated, in its January 2019 Corporate Presentation, that clinical trials for TLANDO met a "key secondary endpoint," a reference to the FDA's standard that no subject in a testosterone replacement therapy trial have maximum testosterone levels measured higher than 2,500 ng/dL.[6] While, as discussed above, Plaintiffs' puzzle-style complaint makes it difficult to precisely determine the alleged reason why this statement is false or misleading, it appears that Plaintiffs are contending that the statement is false because one subject in the DV Study exceeded the maximum 2,500 ng/dL Cmax threshold. (*See* Am. Compl. at ¶ 70.)

Lipocine argues that it was not false or misleading to state that TLANDO had met the key secondary endpoint because the only subject that exceeded the 2,500 ng/dL threshold was a protocol violator that was not eligible to participate in the study. And it points to the fact that the challenged statement in the January 2019 Corporate Presentation was followed immediately by the statement that there were "[n]o *eligible* subjects with T levels >2500 ng/dl." (Emphasis added).

Plaintiffs contend that the statement was still false or misleading, despite Lipocine's disclosure that it was excluding the sole excursion from the 2,500 ng/dL Cmax threshold, because Lipocine failed to disclose that the FDA had rejected Lipocine's position that the ineligible participant should be excluded from the secondary endpoint analysis, that the FDA had previously

[6] While not referenced as an affirmatively false statement in Plaintiffs' opposition memorandum, a similar statement, Statement 14, appeared in the May 2019 Corporate Presentation that is referenced in the complaint. (*See* Am. Compl. at ¶ 80 ("Met primary endpoint").) To the extent Plaintiffs claim that Statement 14 is an actionable misstatement, that claim fails for the same reasons that their claim against Statement 2 fails.

stated publicly that TLANDO had failed to meet all three of the secondary endpoint thresholds, and that Lipocine itself had admitted that TLANDO had failed to meet all three of the secondary endpoint thresholds in other statements.

When read in isolation, Plaintiffs' allegation that Statement 2 is misleading might be of concern. But the amended complaint fails to show, when the challenged statement is read in the context of the rest of the January 2019 Corporate Presentations, how the statement was false or misleading.

As an initial matter, Plaintiffs' assertion that the FDA had rejected Lipocine's contention that the sole subject that had a Cmax that exceeded 2,500 ng/dL should be excluded from the analysis is not supported by the facts alleged in the complaint or that appear in the public records of which the court has taken judicial notice. To the contrary, the amended complaint shows that the FDA itself noted that the sole subject that exceeded 2,500 ng/dL "had a history of cholecystectomy, which was one of the exclusion criteria." (Am. Compl. at ¶ 48.) And while the FDA stated that it was "unclear" whether the protocol violation contributed to the Cmax excursions, there are no alleged facts in the complaint or that appear in the public records that support Plaintiffs' assertion that the FDA "rejected" Lipocine's suggestion that the subject should be excluded from the secondary endpoint analysis.

Furthermore, prior statements in the January 2019 Corporate Presentation made clear that Lipocine's approach to responding to the FDA's secondary endpoint concerns was not to show how TLANDO satisfied the FDA's secondary endpoint criteria in the DV Study. Instead, responding to guidance in the May 2018 CRL, Lipocine had disclosed that it would attempt to justify the non-applicability of those criteria through analyses of existing data. Indeed, Lipocine's

disclosure of its approach to responding to the secondary endpoint concerns raised in the May 2018 CRL appeared in the slide immediately preceding the slide where the second challenged statement appeared.[7]

Thus, when read in context of the rest of the Corporate Presentations, Statement 2 is best understood as a disclosure of how Lipocine intended to use existing data to justify the non-applicability of the secondary endpoints established by the FDA. In that light, the statement is nothing more than a representation regarding Lipocine's own interpretation of the data from the DV Study.

Interpretations of data from clinical studies are "essentially no different than opinions." *See In re Sanofi-Aventis Sec. Litig.*, 774 F. Supp. 2d 549, 567 (S.D.N.Y. 2011). *See also Wolfe v. Aspenbio Pharma, Inc.*, Civil No. 11-cv-00165-REB-KMT, 2012 WL 4040344, *8 (D. Colo. Sept. 13, 2012) (unpublished) (quoting *In re Sanofi-Aventis Sec. Litig.*, 774 F. Supp. 2d at 567). And because "[r]easonable professionals 'may well differ with respect to what constitutes acceptable testing procedures, as well as how best to interpret data garnered under various protocols . . . interpretations of scientific data are not misleading where the interpretation finds reasonable support in the data." *Wolfe*, 2012 WL 4040344 at * 8 (quoting *Noble Asset Mgmt. v. Allos Therapeutics, Inc.*, No. CIVA-04CV-1030-RPM, 2005 WL 4161977 at *11 (D. Colo. Oct. 20, 2005) (unpublished)).

Plaintiffs do not allege that Lipocine did not honestly believe that the ineligible subject should be excluded from Lipocine's own secondary endpoint analysis. Nor do they allege that the

[7] The May 2019 Corporate Presentation similarly references Lipocine's need to provide "[j]ustification for [the] non-applicability of Cmax based missed secondary endpoints" in the same slide where the challenged statement appears. (Am. Compl. at ¶ 80.)

existing data from the DV Study did not support excluding the ineligible subject from the analysis Lipocine was putting forward to justify the non-applicability of the FDA's standards. Nothing in the January 2019 or May 2019 Corporate Presentations suggests that Statement 2 was intended to be a representation regarding how the FDA viewed data from the DV Study, or how the FDA would view Lipocine's attempt to justify the non-applicability of the FDA's own secondary endpoint thresholds. Accordingly, the amended complaint does not allege facts sufficient to show that Statement 2 is actionable under § 10(b).

ii. *TLANDO's Other Secondary Endpoints Were Generally Consistent with Other Approved Products. (Statements Nos. 3 and 13)*

Plaintiffs also challenge statements in the January 2019 Corporate Presentation (Statement No. 3) and a March 27, 2019 Press Release (Statement No. 13) that represented that TLANDO's other secondary endpoints were generally consistent with other approved products. (Am. Compl. at ¶¶ 72, 78.) Plaintiffs suggest, in their amended complaint, that these statements were a reference to the per dose measure of TLANDO's secondary endpoints, since "the 'per dose' findings were arguably consistent with some other approved products, [while] the 'per day' findings were significantly worse than any other approved product." (*Id*. at ¶ 62.) Thus, Plaintiffs allege, the statement "reinforced the false and misleading impression that the 'per dose' analysis was crucial—if not determinative—for resolution of the Cmax deficiency." (*Id*.)

Neither the January 2019 Corporate Presentation nor the March 27, 2019 Press Release, however, make any reference to either the per dose or the per day measure of TLANDO's secondary endpoints. It is difficult to see how statements regarding the consistency of TLANDO's clinical trial results with other products could emphasize the importance of an analytical measurement of clinical data that appears nowhere in the documents where the challenged

representations are made. While it may be the case that Lipocine relied on the per dose measure when it concluded that TLANDO's secondary endpoints were "generally consistent" with other approved testosterone products, there is no information in the January 2019 Corporate Presentation or the March 27, 2019 Press Release that suggests that is the case. Indeed, the subject of the March 27, 2019 Press Release was the results of Lipocine's ABPM study and makes no mention of Cmax. Thus, Plaintiffs' assertion that Statements 3 and 13 constitute false or misleading statements about the significance of the per dose measure of secondary endpoints is based on nothing but speculation at best.

Even if Plaintiffs are correct about how Lipocine determined that TLANDO's secondary endpoints were "generally consistent" with other approved products, the statement is not actionable under § 10(b) because it constitutes nothing more than corporate puffery. It is well established that statements that are "mere puffing" and "not capable of objective verification" are immaterial for purposes of § 10(b) liability and, therefore, cannot provide the basis for a claim of securities fraud. *Ind. Pub. Ret. Sys. v. Pluralsight, Inc.*, 45 F.4th 1236, 1248-49 (10th Cir. 2022) (quoting *In re Level 3 Commc'ns, Inc. Sec. Litig.*, 667 F.3d 1331, 1339 (10th Cir. 2012)). "Vague, optimistic statements are not actionable because reasonable investors do not rely on them in making investment decisions." *Id*. at 1249 (quoting *Level 3*, 667 F.3d at 1339).

In its recent decision in *Pluralsight*, the Tenth Circuit explained the distinction between a statement that is false and misleading, and therefore actionable under § 10(b), and non-actionable puffing. That distinction lies in whether the statement is "grounded in concrete metrics or other objectively verifiable data." *Id*. Thus, statements such as (1) "the majority of the integration was complete, ahead of plan and under budget"; (2) "a majority of the physical network interconnection

are completed"; (3) "the integration efforts were 80%, 90% done"; and (4) "most of the physical integration . . . is not complete" are all statements that cross the line from puffery to actionable misrepresentations, while a representation that a project is "progressing well" does not. *Id*. (citing *Level 3*, 667 F.3d at 1340) (internal quotation marks and alterations omitted). The clear distinction between those statements that the Tenth Circuit has held as actionable under the securities laws, and those that it has identify as mere puffery, is that the actionable statements can be verified or proven false through a comparison to objective facts.

Against that framework, the Tenth Circuit evaluated a claim similar to the one raised by Plaintiffs here. In *Pluralsight*, the plaintiffs alleged that the defendants' statements in its Form 10-K, under a heading entitled "Growth Strategy," representing that Pluralsight had a "large direct sales force" and was "able to drive substantial increases in the productivity and effectiveness of [its] sales personnel over time" were false or misleading because defendants knew that "Pluralsight had an insufficient number of sales representatives to sustain its billing growth." *Id*. at 1253-54. The plaintiffs argued that these statements were not mere puffery because they could be verified by referencing Pluralsight's "ramp capacity plan, billings pipeline records, and sales quota records." *Id*. at 1254. Thus, the plaintiffs argued, the statement that Pluralsight's sales force was "sufficiently 'large' to be 'effective' and 'productive'" was objectively verifiable. *Id*.

The Tenth Circuit rejected this argument, explaining that the defendants' "representations about the size, efficiency, and productivity of the sales force do not implicitly reference any of Pluralsight's internal metrics, such as its 'ramp capacity plan, billings pipeline records, and sales quota records.'" *Id*. Thus, the court held that the statements were "merely rosy affirmations and no

reasonable investor could find them important." *Id*. (internal quotation marks and alterations omitted).

Here, Plaintiffs' claim that Pluralsight's representations that TLANDO's secondary endpoints were "generally consistent" with other approved testosterone products suffers from the same flaw that undermined the plaintiffs' claim in *Pluralsight*. The challenged statements do not make any reference, express or implicit, to the per day or per dose measure of TLANDO's secondary endpoints. Moreover, the statement is not objectively verifiable against either measure. While Plaintiffs are certainly entitled to disagree with Lipocine's assessment that TLANDO's secondary endpoints were "generally consistent" with other products, there is no objective criteria against which the challenged statement can be measured.[8] Accordingly, Statements 3 and 13 are nothing more than puffery and, therefore, are not actionable under § 10(b).

2. Omissions

The failure to disclose a material fact can constitute an actionable violation of Section 10(b) and Rule 10b-5 if the defendant had a duty to disclose the omitted information. *Employees' Retirement Sys. of R.I. v. Williams Companies, Inc.*, 889 F.3d 1153, 1162 (10th Cir. 2018).

[8] Plaintiffs contend that there is evidence that the market was actually misled by Lipocine's reference to the per dose measure of secondary endpoints and its comparison of TLANDO to other testosterone products, citing statements from two market analysts that expressed surprise that approval of TLANDO had been denied when Jatenzo, another oral testosterone supplement, had been approved a few months earlier. (Am. Compl. at ¶¶ 67-69.) According to Plaintiffs, these analysts were misled into comparing Jatenzo's per day secondary endpoint measurements to TLANDO's per dose measurements. (*Id*.) Plaintiffs, however, have not alleged any facts to show that these analysts relied on Statement 3. Indeed, it is difficult to see how that could be the case, since Jatenzo was not an approved product at the time the statements in the January 2019 Corporate Presentation were made. Moreover, Plaintiffs have cited no authority to support the conclusion that a vague statement of corporate puffery can be transformed into a material misrepresentation that is actionable under § 10(b) based on evidence that third-party market analysts made a mistake about the significance of particular data that is not referenced in the statement.

Plaintiffs argue, broadly, that once Defendants chose to provide information regarding TLANDO and the secondary endpoint results from its clinical trials, they had "a duty to provide complete and non-misleading information" regarding those topics. (*See* Mem. Opp. Mot. to Dismiss at 15, ECF No. 50.)

Plaintiffs overstate the law. Indeed, the Tenth Circuit has specifically rejected the idea that "once a disclosure is made, there is a duty to make it complete and accurate." *Emps.' Ret. Sys. of R.I.*, 889 F.3d at 1164 (citing *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002)).) Instead, "Rule 10b-5 'prohibits *only* misleading and untrue statement, not statements that are incomplete.'" *Id*. (quoting *Brody*, 280 F.3d at 1006)) (internal alterations omitted, emphasis in original). The court explained that "[t]o require that statements be 'complete' would be to impose an excessive burden since 'no matter how detailed and accurate disclosure statements are, there are likely to be additional details that could have been disclosed but were not.'" *Id*. (quoting *Brody*, 280 F.3d at 1006)) (internal alterations omitted, emphasis in original).

Thus, contrary to Plaintiffs' assertions, the failure to provide *complete* information in a disclosure statement is not actionable under § 10(b). Instead, "[t]o be actionable under the securities laws, an omission must be misleading; in other words it must affirmatively create an impression of a state of affairs that differs in a material way from the one that actually exists." *Id*.

As discussed above, Plaintiffs' amended complaint fails to specifically explain how any of the statements challenged in the amended complaint were misleading in light of the alleged omissions. This failure in pleading is sufficient, by itself, to warrant dismissal. Nevertheless, the court will attempt to resolve the motion on its merits by analyzing whether any of the challenged

statements identified in the amended complaint were misleading in light of Defendants' purported failure to disclose the alleged omissions.

i. *The FDA's Secondary Endpoint Thresholds Are Measured on a "Per Day" Basis, not a "Per Dose" Basis.*

Plaintiffs first claim that investors were misled as a result of Defendants' purported failure to disclose that the FDA evaluated TLANDO's secondary endpoints based on a "per day" measure of Cmax, as opposed to a "per dose" measure. According to Plaintiffs, this omission gave investors the false impression that TLANDO's secondary endpoint deviations were not a significant impediment to FDA approval.

As an initial matter, the court must consider whether Plaintiffs have adequately alleged facts to show that the purportedly omitted information was true. False information is, by definition, immaterial. And failing to disclose information that is untrue is not misleading. Defendants had no duty to disclose information that was not true.

Here, the amended complaint does not allege sufficient factual material to show that the FDA had a policy of only considering Cmax secondary endpoint data based on a per day measure. In the absence of such factual allegations, the court is left with only Plaintiffs' conclusory assertion that the FDA's supposed policy of only considering the per day measure of Cmax is a material fact that Defendants failed to disclose. Such conclusory assertions do not state a valid claim for relief.

Nevertheless, for the sake of further analyzing the sufficiency of Plaintiffs' claims, the court will assume that such a policy existed and that Defendants were aware of it. Even under such an assumption, the PSLRA requires Plaintiffs to specifically identify which of Defendants' statements are false or misleading in light of the purported omission. 15 U.S.C. § 78u-4(b)(1).

Plaintiffs have not identified which of the challenged statements identified in the amended complaint were misleading in light of Defendants' alleged failure to disclose that the FDA would only consider the per day measure of TLANDO's Cmax secondary endpoints or the reasons why any of the challenged statements were misleading.

Presumably, however, Plaintiffs would contend that any statements made by Defendants regarding the per dose measure of TLANDO's secondary endpoints required Defendants to disclose that the FDA would not consider such measures when evaluating whether TLANDO met the pre-determined secondary endpoint guidelines. This would implicate challenged statements 7, 8, and 9. These statements appear in each of Lipocine's annual and quarterly SEC filings during the putative class period. Statement 7 discloses the FDA's secondary endpoint thresholds. Statement 8 discloses that Lipocine conducted both a per dose and per day analysis of TLANDO's secondary endpoints. And Statement 9 discloses the specific secondary endpoint results for TLANDO under the per dose measure. Notably, Plaintiffs do not dispute the accuracy of any of these statements.

None of these statements provide any information regarding how the FDA would view Lipocine's per dose measure of TLANDO's secondary endpoints. They do not suggest that the FDA would accept Lipocine's per dose analysis. Nor do they suggest that the FDA would ignore the per day results.

Moreover, even if an investor reviewing Statements 7-9 in isolation might believe that Lipocine was representing that the per dose measure of TLANDO's secondary endpoints would, alone, satisfy the FDAs secondary endpoint requirements, they should have been disabused of such

a notion when reading the challenged statements in the context of the rest of Lipocine's annual and quarterly statements.

On the page immediately preceding Lipocine's disclosure of TLANDO's per dose secondary endpoint results, Lipocine's annual and quarterly reports disclose the results of the August 2017 NDA and the FDA's issuance of a CRL for that application in May 2018. (*See, e.g.*, Blair Decl. at Ex. E, p. 4.) In the discussion, Lipocine discloses that TLANDO's failure to meet the FDA's secondary endpoint thresholds was one of the deficiencies cited by the FDA in its denial of the August 2019 NDA. (*Id*.) More specifically, the reports disclose that the FDA indicated that Lipocine's August 2019 NDA was deficient in that Lipocine needed to "verif[y] the reliability of Cmax data and *provid[e] justification for non-applicability of the agreed-upon and prespecified Cmax secondary endpoints for TLANDO*." (*Id*.) (emphasis added). Furthermore, the report indicated that Lipocine intended to address the deficiencies with respect to TLANDO's secondary endpoints identified in the 2018 CRL by "performing additional analyses of existing data in order to address the Cmax deficiency." (*Id*.)

Thus, when read in context, it should have been clear to any reasonable investor that Statements 7-9 were made to disclose how Lipocine was addressing the Cmax deficiencies that led, in part, to the FDA's denial of the August 2017 NDA, not to mislead investors into believing that no such deficiencies existed. Indeed, as the reports indicated, the FDA requested that Lipocine *justify the non-applicability* of the agreed-upon and prespecified Cmax secondary endpoints for TLANDO. When read in such context, Lipocine's simple disclosure of the per dose secondary endpoint measures could not have misled a reasonable investor with respect to what measure the

FDA relied on in determining that TLANDO failed to meet the secondary endpoint measures when it issued the 2018 CRL.

Accordingly, even assuming that the FDA had a policy of considering only the per day measure of TLANDO's Cmax secondary endpoints that Defendants were aware of, Lipocine's disclosure of the per dose measure did not impose a duty to disclose such a policy. Therefore, Statements 7-9 were not misleading and do not provide a basis for Section 10(b) liability.

ii. *Defendants' Failure to Disclose Specific "Per Day" Data*

Plaintiffs also allege that Defendants misled investors by failing to specifically disclose data from the per day analysis of TLANDO's secondary endpoints.

Again, Plaintiffs fail to specifically identify which of the challenged statements were misleading in light of the purported omission of such data. Presumably, however, Plaintiffs would contend that Defendants' disclosure of specific data for the per dose measure of TLANDO's secondary endpoints, and its more general disclosure that TLANDO did not meet the FDA's secondary endpoint thresholds under the per day measure, required a more specific disclosure of the per day data. If correct, Plaintiffs' allegations would implicate Statements 9 and 10, both of which appear in each of Lipocine's annual and quarterly reports during the class period.

As discussed above, Statement 9 discloses specific measurements of TLANDO's secondary endpoints under the per dose measurement. Statement 10 is a disclosure that "[d]eviations from the predetermined limits in the DV Study were observed in the Cmax per day dose analysis for these thresholds." (Am. Compl. at ¶¶ 76, 84, & 90.) Plaintiffs do not contest the accuracy of either of these statements.

When read in context, the court fails to see how either statement could be misleading in light of Defendants' purported failure to disclose specific data regarding the per day measure of TLANDO's secondary endpoints. As discussed above, the purpose of these statements was to show how Lipocine was attempting to provide "justification for the non-applicability" of the FDA's secondary endpoint thresholds through "analysis of existing data." (Blair Decl. at Ex. E, p. 4.) The reports disclosed, on the previous page, that the August 2017 NDA was rejected in part for failure to meet the FDA's thresholds. Providing specific data regarding the per day measure would only confirm what Lipocine had already disclosed—that the per day measure of TLANDO's secondary endpoints did not meet the FDA's pre-established guidelines. Providing such information would not have been helpful to show how Lipocine was addressing deficiencies identified in the 2018 CRL, and Defendants' failure to include such information in its annual and quarterly reports was not misleading with respect to that approach.

Moreover, as Defendants correctly point out in their motion, the specific data regarding the per day measure of TLANDO's secondary endpoint thresholds was made publicly available by both Lipocine and the FDA in each party's respective briefing and presentation materials provided to the BRUDAC committee in January 2018. A reasonable investor that was interested in the comparison of the per day analysis with the per dose analysis of TLANDO's secondary endpoints could have referred to that information.

Defendants "were not obliged to reproduce a comprehensive enumeration of adverse events every time they mentioned" TLANDO's secondary endpoint results. *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 547 (S.D.N.Y 2015). Given the total mix of information made publicly available, Defendants' failure to provide specific data regarding the per day measure of TLANDO's

secondary endpoints in its annual and quarterly reports during the class period could not have misled a reasonable investor regarding Lipocine's approach to addressing deficiencies identified in the 2018 CRL.

Accordingly, Lipocine's disclosure of specific data regarding the per dose measure of TLANDO's secondary endpoints and its disclosure that TLANDO failed to meet the FDA's secondary endpoint thresholds under the per day measure did not give rise to a duty to disclose specific data regarding the per day analysis of TLANDO's secondary endpoints. Statements 9 and 10 are not actionable as a result of Defendants' omission of such data.

iii. *The FDA Had Never Approved a Comparable Testosterone Product with Secondary Endpoint Deviations as Significant as TLANDO's*

Plaintiffs also contend that Defendants misled investors by failing to disclose that the FDA had never approved a testosterone product that was comparable to TLANDO and that had secondary endpoint deviations as significant as TLANDO's.

Plaintiffs' amended complaint again fails to specifically identify which of Defendants' statements were false or misleading in light of Defendants' purported failure to disclose that the FDA had never approved a produce with Cmax secondary endpoint results comparable to TLANDO's. Plaintiffs would presumably point to Statements 3 and 13 to support their claim that such an omission was actionable under Section 10(b) and Rule 10b-5, which represented that TLANDO's secondary endpoints were "generally consistent" with approved products.

But the omission alleged by Plaintiffs—that no testosterone with *comparable* secondary endpoints had been approved—directly contradicts Lipocine's statements that TLANDO's secondary endpoints were *generally consistent* with approved products. It would be contradictory and illogical for Defendants to state that TLANDO's secondary endpoint results are both

"generally consistent" and "not comparable" with those of other approved testosterone products. Thus, Plaintiffs' allegation that Defendants' failure to disclose the purported fact that no comparable product had been approved by the FDA must be understood as a restatement of its argument that Statements 3 and 13 are affirmatively false.

As explained above, Statements 3 and 13 are not actionable of their own accord because they are not objectively verifiable and are, therefore, non-actionable puffery. (*See supra* Part I.B.1.ii.)

The purported omission identified by Plaintiffs is equally unverifiable. Plaintiffs do not identify any objective criteria by which their assertion that the secondary endpoint results of approved products were not "comparable" can be measured. Thus, Plaintiffs' alleged omission would also be a puffing statement.

Plaintiffs have cited no authority to support the conclusion that a non-actionable puffing statement can be transformed into an actionable misrepresentation as a result of a defendant's failure to make an equally non-verifiable, and contradictory, puffing statement. Such a result would be illogical.

Even if Statements 3 and 13 were not unactionable under the puffery doctrine, they are opinion statements that are also typically unactionable. In *Omnicare, Inc. v. Laborers District Council Construction Industry Pension Fund*, 575 U.S. 175 (2015), the Supreme Court identified the narrow circumstances when a statement of opinion may be actionable under Section 11 of the

Securities Act, which prohibits making false or misleading statements or omissions in a registration statement.[9]

First, an opinion statement may be actionable if the person expressing the opinion does not actually hold the opinion expressed. *Id*. at 185-86. Plaintiffs have not alleged any facts that would plausibly show that Defendants did not honestly believe that TLANDO's secondary endpoint results were generally consistent with other approved products. Thus, Statements 3 and 13 are not actionable on this basis.

Second, when an opinion statement contains an embedded statement of fact, the statement may be actionable if the factual portion of the statement is untrue. *Id*. Taking an example from *Omnicare*, if the CEO of a television manufacturer says, "I believe our TVs have the highest

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[9] The Supreme Court's holding in *Omnicare* was limited to claims brought under Section 11 of the Securities Act. Some courts have questioned whether *Omnicare* applies to claims brought under Section 10(b), noting that Section 11 imposes strict liability for false or misleading statements or omissions while "scienter is an essential element of a Section 10(b) cause of action." *Firefighters Pension & Relief Fund of the City of New Orleans v. Buhlmahn*, 147 F. Supp. 3d 493, 527-28 (E.D. La. 2015) (declining to apply *Omnicare* to forward-looking statements of opinion). *Cf. In re Amarin Corp. PLC Sec. Litig.*, No. 21-2071, 2022 WL 2128560 at *3 n.7 (3d Cir. June 14, 2022) (unpublished) (noting that the court had "not yet decided" whether the framework in *Omnicare* is applicable to claims under § 10(b) of the Exchange Act."); *Lord Abbett Affiliated Fund, Inc. v. Navient Corp.*, 363 F. Supp. 3d 476, 496 (D. Del. 2019) (Noting that Third Circuit had twice declined to decide whether *Omnicare* applies to a Section 10(b) claim and declining to decide the issue in the first instance).

The court notes that the majority opinion in *Omnicare* itself appears to provide a basis for distinguishing *Omnicare's* holding from Section 10(b) cases on the grounds that Section 11 imposes strict liability. *See* 575 U.S. 175 at 192 n.11 (responding to disagreement in Justice Scalia's partial concurrence by noting that "§ 11 discards the common law's intent requirement").

Nevertheless, while the Tenth Circuit has never directly considered whether *Omnicare's* holding should be applied to claims brought under Section 10(b), it has applied *Omnicare* to find opinion statements actionable under Section 10(b) in a recent case. *See S.E.C. v. GenAudio, Inc.*, 32 F.4th 902, 924 (10th Cir. 2022) (citing *Omnicare*, 575 U.S. at 188-89) ("The securities laws impose a personal obligation on corporate executives . . . to sufficiently grounds their communications in facts."). Accordingly, the court will follow the Tenth Circuit's lead and apply the holding of *Omnicare* to Plaintiffs' claims in this action.

resolution available because we use a patented technology to which our competitors do not have access," the statement of opinion would be actionable if the company did not, in fact, use a patented technology in their televisions. *Id*. at 185. Plaintiffs have not identified an embedded statement of fact in Statements 3 and 13 that they allege is untrue. Therefore, Statements 3 and 13 are not actionable under this theory either.

Finally, *Omnicare* held that a pure statement of opinion, even if honestly believed, may be misleading and actionable under Section 11 if it conveys facts about how the speaker formed the opinion that are misleading in light of omitted facts. *Id*. at 189-189. In *Omnicare*, the Supreme Court held that the defendants' statement that they believed their conduct was lawful could be "misleadingly incomplete" if that opinion did not rest on "some meaningful legal inquiry—rather than, say, on mere intuition, however sincere." *Id*. at 189. On that basis, the Court remanded the case to the Sixth Circuit to determine whether Omnicare's statements about its legal compliance were misleading in light of omitted facts. *Id*. at 195-96.

The Court in *Omnicare* emphasized that its holding did not impose a general disclosure requirement. "An opinion statement . . . is not necessarily misleading when an issuer knows, but fails to disclose, some fact cutting the other way." *Id*. at 189. Nor does a reasonable investor expect that "*every* fact known to an issuer supports its opinion statement." *Id*. at 190. Instead, an opinion statement is only actionable "when an issuer's failure to include a material fact has rendered a published statement misleading." *Id*. at 194. To state a claim based on a misleading opinion statement, an "investor must identify particular (and material) facts going to the basis for the issuer's opinion—facts about the inquiry the issuer did or did not conduct or the knowledge it did

or did not have—whose omission makes the opinion statement at issue misleading to a reasonable person reading the statement fairly and in context." *Id*.

The Supreme Court also emphasized that determining whether an opinion statement is misleading in light of an alleged omission "always depends on context." *Id*. at 190. Thus, an investor reading an opinion expressed in a formal disclosure, such as a registration statement, may have different expectations regarding the basis for the opinion than an opinion appearing in a less formal context. *See Id*. at 190-91 ("[A]n omission that renders misleading a statement of opinion when viewed in a vacuum may not do so once that statement is considered, as is appropriate, in a broader framework.").

Here, Plaintiffs have not identified any facts about Defendants' formation of the opinion that TLANDO's secondary endpoint and ABPM results were "generally consistent" with those of other approved products that would render such an opinion misleading in the context in which they appear—a corporate presentation and press release. Nor have they identified any facts, known to Defendants, that would render Statements 3 and 13 misleading when omitted.

Instead, Plaintiffs claim that Statements 3 and 13 are misleading because of Defendants' failure to express Plaintiffs' own opinion regarding the consistency of TLANDO's secondary endpoint results with other products. *Omnicare* does not impose a general duty on Defendants to express an opinion that they disagree with, or to disclose that others may disagree with their assessment. Thus, *Omnicare* does not apply to make Statements 3 and 13 actionable under Section 10(b).

iv. *The FDA Rejected Exclusion of a Protocol Violator in TLANDO's DV Study.*

Plaintiffs also allege that Defendants' statements were misleading as a result of Defendants' failure to disclose that the "FDA had rejected the suggestion that a protocol-violating subject should be removed from the stat to allow for TLANDO to have met the 'key' 25000 ng/dL limit secondary endpoint." (Opp. at 13, ECF No. 50.) Plaintiffs would presumably argue that such an omission made Statements 2 and 14, which state that TLANDO met a "key secondary endpoint," misleading.

As discussed above, Plaintiffs' contention that the FDA had rejected the exclusion of the protocol violation from TLANDO's secondary endpoint analysis is not supported by the record. Nor is it supported by any specific factual allegations made in Plaintiffs' complaint. At best, the FDA raised questions about whether the protocol violator should be excluded from the secondary endpoint analysis, a fact that was disclosed in the FDA's publicly available material submitted to the BRUDAC committee.

Defendants cannot be liable for failing to disclose a fact that was not true. Thus, Statements 2 and 14 cannot be actionable on the basis of Plaintiffs' omissions theory either.

v. *The Results of the DF Study Were Irrelevant to FDA Approval*.

Finally, Plaintiffs claim that Defendants' failure to disclose that "the fact that the DF Study met the secondary endpoints was irrelevant to the FDA's consideration of the TLANDO NDA" was misleading, presumably in light of Defendants' statement that "[t]he DF study SS met all Cmax thresholds in per dose and per day dose analyses"—Statement 12.

The amended complaint, however, does not allege facts that would support Plaintiffs' assertion that the DF Study was irrelevant to the FDA's consideration of the May 2019 NDA. The

only fact alleged in the amended complaint that might be construed to suggest that the DF Study was irrelevant is the allegation that Lipocine submitted the August 2017 NDA "based on the results of the DV Study." (Am. Compl. at ¶ 44, ECF No. 44.) But the complaint says nothing about the relevance of the DF Study to the May 2019 NDA that is the subject of Plaintiffs' claims.

Moreover, each of Lipocine's annual and quarterly SEC reports during the alleged class period, which is where Statement 12 appears, disclose that the August 2017 NDA was based on the DV Study. (*E.g.*, Blair Decl. at Ex. E, p. 4.) And they disclose that the DV Study would be Lipocine's "pivotal efficacy clinical study" for the May 2019 NDA resubmission. (*E.g.*, *id*. at Ex. E, p. 5.) Thus, the very information that Plaintiffs rely on to support their contention that the DF Study was irrelevant appears in the same document that Statement 12 appears in. Plaintiffs identify no other basis for concluding that the DF Study was not relevant to the FDA's consideration of the May 2019 NDA. No reasonable investor, reading Statement 12 in the context in which it appears, could conclude that Statement 12 was misleading with respect to the relevance of the DF Study to the FDA's consideration of the May 2019 NDA. Therefore, Statement 12 is not actionable on the grounds that Defendants omitted the information alleged by Plaintiffs. The information was not omitted

Given that none of the statements or omissions identified by Plaintiffs in their amended complaint provide a sufficient basis for holding Defendants liable under Section 10(b) or Rule 10b-5, Defendants are entitled to dismissal of this action.

C. Scienter

Defendants also argue that Plaintiffs' action should be dismissed because the amended complaint fails to adequately allege the requisite scienter for liability under Section 10(b) and Rule 10b-5.

To state a valid claim under Section 10(b), Plaintiffs were required to allege facts showing that "the defendant acted with scienter, that is, with intent to defraud or recklessness." *In re Zagg*, 797 F.3d at 1200 (emphasis omitted). And, as is the case with allegations regarding falsity, the PSLRA imposes a heightened pleading requirement for allegations of scienter, requiring that "complaints shall, with respect to each act or omission alleged to violate [Section 10(b)], state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2).

When considering whether a complaint's allegations of scienter meet the PSLRA's heightened standard, the court is required to "engage in a comparative evaluation." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 314 (2007). The court must consider "not only inferences urged by the plaintiff . . . but also competing inferences rationally drawn from the facts alleged." *Id*. "An inference of fraudulent intent may be plausible, yet less cogent than other, nonculpable explanations for the defendant's conduct." *Id*. Thus, to qualify as a "strong" inference that meets the requirements of the PSLRA, an inference of scienter urged by a plaintiff "must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Id*.

In a case, like this one, where fraud is based on an alleged failure to disclose material information, the PSLRA requires more than an allegation that the defendant knew the facts that

were allegedly omitted. *See City of Philadelphia v. Fleming Cos., Inc.*, 264 F.3d 1245, 1260 (10th Cir. 2001) ("[A]llegations that the defendant possessed knowledge of facts that are later determined by a court to have been material, without more, is [sic] not sufficient to demonstrate that the defendant intentionally withheld those fact from, or recklessly disregarded the importance of those facts to, a company's shareholders in order to deceive, manipulate, or defraud."). Instead, "to establish scienter in a securities fraud case alleging non-disclosure of potentially material facts, the plaintiff must demonstrate: (1) the defendant knew of the potentially material fact, and (2) the defendant knew that failure to reveal the potentially material fact would likely mislead investors." *Id*. at 1261.

In the context of a claim for securities fraud, a plaintiff that intends to rely on a theory of recklessness to establish scienter must allege facts showing "conduct that is an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *Id*. at 1258. And where a plaintiff relies on a recklessness theory to establish securities fraud based on the non-disclosure of material information, the alleged facts must show "the defendant's knowledge of a fact that was so obviously material that the defendant must have been aware both of its materiality and that its non-disclosure would likely mislead investors." *Id*.

The amended complaint fails to allege facts that are sufficient to meet the PSLRA's heightened pleading standard with respect to scienter.

The complaint does not connect any of Plaintiffs' particular scienter allegations to any of the specific statements or omissions challenged under Section 10(b). Instead, when Plaintiffs' conclusory allegations are disregarded, as they must be, the amended complaint alleges, at best,

that Defendants had full knowledge of the clinical trial results relating to TLANDO, including the failure of TLANDO to meet the FDA's secondary endpoint standards in the DV Study, and its progress through the FDA approval process. (*See* Am. Compl. at ¶¶ 97-102.)

As the Tenth Circuit has held, the PSLRA requires more than an allegation that Defendants had knowledge of facts that they allegedly failed to disclose. Thus, Plaintiffs' knowledge allegations are not sufficient to satisfy the pleading standard for scienter.

In an apparent attempt to bolster their inadequate scienter allegations, Plaintiffs allege that Defendants had a motive to deceive investors into believing the prospects of TLANDO's approval was greater than it was. According to Plaintiffs, Lipocine was desperate to raise capital at the beginning of and throughout the class period in order to service its debt obligations under the SVB Loan. (Am. Compl. at ¶¶ 55-57, 60.) To meet this need for capital, Lipocine, under Plaintiffs' theory, "turned to selling shares of the Company's common stock to finance its operations." (*Id.* at ¶ 57.) And "to generate interest in its stock, the Company decided to prematurely push a resubmission of the TLANDO NDA despite not having resolved the issues identified in the 2018 CRL." (*Id.*)

There are several reasons why Plaintiffs' motive allegations are insufficient to meet the standards for pleading scienter.

First, while allegations regarding motive and opportunity may be relevant to establishing a defendant's scienter, they are not sufficient by themselves to satisfy the PSLRA's pleading requirement. *Fleming Cos.*, 264 F.3d at 1263 (10th Cir. 2001) ("[M]otive and opportunity pleadings are relevant to a finding of scienter, but they do not constitute a separate, alternative method of pleading scienter.") (citations omitted). Instead, to the extent they are relevant, motive

allegations must be considered along with the totality of Plaintiffs' other scienter allegations to determine whether a strong inference of scienter can be drawn. *Id*. at 1262 ("[C]ourts must look to the totality of the pleadings to determine whether the plaintiffs' allegations permit a strong inference of fraudulent intent. Allegations of motive and opportunity may be important to that totality, but are typically not sufficient in themselves to establish a 'strong inference' of scienter.") (citation omitted).

Second, allegations of "generalized motives shared by all companies that are not specifically and uniquely related to [the Defendants] in particular, are unavailing." *Id*. at 1269. Here, while Plaintiff has alleged specific facts regarding Lipocine's particular debt situation, the need to raise capital for operations or to service debt is not unique to Lipocine.[10] It is a general need that nearly all companies, particularly start up pharmaceutical companies, would likely have. If Plaintiffs could satisfy their heightened pleading burden with respect to scienter by merely alleging that Lipocine needed capital to service debt, then scienter could be established against any other start up pharmaceutical company in similar need of cash. "The PSLRA was obviously intended to eliminate frivolous securities litigation through its heightened scienter pleading requirements." *Id*. at 1263. If that standard could be defeated with such generalized allegations, that purpose would be defeated.

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[10] Plaintiffs argue that their allegations regarding Lipocine's need to raise capital to service the SVB Loan are not allegations regarding a generalized business motive, but are allegations regarding Lipocine's specific financial concerns. In support, they cite *Medina v. Clovis Oncology, Inc.*, 215 F. Supp. 3d 1094, 1128 (D. Colo. 2017). The court does not find *Medina* persuasive. While Plaintiffs' allegations regarding Lipocine's particular need for capital, like those at issue in *Medina*, are more specific than the allegations recited by the Tenth Circuit in the *Fleming* decision, they still only amount to an allegation that Lipocine needed capital to continue pursuing FDA approval of its drug. This is a motive that is shared by many small pharmaceutical companies—not one that was unique to *Lipocine*.

Finally, Plaintiffs' motive allegations are undermined, to a large extent, by material that was publicly available before Lipocine obtained the SVB Loan. The court has taken judicial notice of a press release issued by Lipocine in June 2017, in which Lipocine made statements regarding the per dose secondary endpoint results from the DV Study that are nearly identical to those that were made during the class period and that are challenged as fraudulent by Plaintiffs in this suit.[11] (*See* Blair Decl. at Ex. I, ECF No. 48-10.) But the SVB Loan was not obtained by Lipocine until January 2018. (Am. Compl. at ¶ 55.) And Lipocine's supposed desperation for capital, as a result of the need to begin making payments of principal on the SVB Loan, did not arise until January 2019. (*Id*. at ¶¶ 56-57.)

If it was the need to service the SVB Loan that motivated Lipocine to misrepresent the results of the DV Study by emphasizing the per dose measure of TLANDO's secondary endpoints over the per day measure, Plaintiffs have offered no explanation of why Lipocine made nearly identical statements before that need ever arose.

When viewed with the totality of the pleadings, Plaintiffs' motive allegations do not lend support to a strong inference of scienter. Plaintiffs have not alleged facts demonstrating that Defendants had an actual intent to defraud or deceive. Nor have they alleged facts showing that Defendants' conduct was so extreme and out of the ordinary as to be considered reckless for purposes of a securities fraud claim.

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[11] Plaintiffs suggest, in their opposition, that the June 2017 Press Release is just another example of Lipocine misleading investors regarding the prospects of FDA approval, undermining Lipocine's claim that the full results of the DV Study were disclosed publicly in the context of the BRUDAC Meeting and 2018 CRL. (Opp. at 24, ECF No. 50.) This assertion, which does not appear in the amended complaint, however, is not supported by any allegations of fraudulent intent on the part of Defendants.

This is particularly evident when Plaintiffs' theory of scienter is compared to competing inferences, as required by *Tellabs*.

Defendants have suggested an alternative inference of scienter. Defendants argue that rather than making the challenged statements with the intent to deceive investors into believing that FDA approval was not exceedingly unlikely, the statements were made in an attempt to explain to investors how Lipocine intended to address the deficiencies identified in the 2018 CRL. And specifically, with respect to TLANDO's secondary endpoint deficiencies, to explain how Lipocine intended to justify the non-applicability of the FDA's secondary endpoint standard by performing additional analysis of existing data.

The court finds Defendants' explanation of its intent when making the challenged statements to be cogent and more plausible than Plaintiffs' theory or fraudulent intent, given the facts alleged and the documentation the court has taken judicial notice of. As discussed in more detail above, Defendants' discussion of the per dose measure of TLANDO's secondary endpoints can be viewed as an attempt to explain to investors how it intended to persuade the FDA to approve TLANDO despite its failure to meet the secondary endpoint thresholds under a per day analysis. This would be consistent with other statements in Lipocine's annual and quarterly reports, as well as statements appearing in Lipocine's corporate presentations and press releases, which disclosed that TLANDO failed to meet the FDA's secondary endpoint thresholds under a per day analysis and indicated that Lipocine intended to address that deficiency by justifying the non-applicability of those thresholds through analysis of existing data.

Such an inference is more plausible, given the facts, than Plaintiffs' generalized and conclusory allegations that Defendants' intended to deceive investors regarding the likelihood of

FDA approval. Accordingly, the court concludes that Plaintiffs' have failed to adequately allege scienter in accordance with the PSLRA's heightened standard. This constitutes an additional, and independent, basis for granting Defendants' motion.

D. Loss Causation

Finally, Defendants argue that the amended complaint should also be dismissed because Plaintiffs' have failed to adequately allege loss causation. The court agrees.

"Loss causation . . . is the causal link between the alleged misconduct and the economic harm ultimately suffered by the plaintiff." *In re Williams Sec. Litig-WCG Subclass*, 558 F.3d 1130, 1136 (10th Cir. 2009) (citation omitted). To plead loss causation in a securities fraud case, a plaintiff must do more than allege an inflated purchase price of the defendant's securities. *Id*. at 1136. Instead, plaintiffs must allege facts showing a causal connection between their actual loss and the defendant's purported misrepresentations. *Id*. at 1136-37. Adequately pleading loss causation is essential because "[t]he securities laws are not meant 'to provide investors with broad insurance against market losses, but to protect them against those economic losses that misrepresentations actually cause.'" *Id*. at 1137 (quoting *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 345 (2005)).

There are multiple methods of proving loss causation in a securities fraud case. Plaintiffs identify two methods in their briefing: (1) by showing that their loss is the result of "a corrective disclosure" that "reveals the fraud to the public" and (2) through a theory of "materialization of a concealed risk" in which "a plaintiff . . . shows that the defendant's misrepresentation concealed a risk that caused a loss for the plaintiff when the risk materialized." (Opp. at 24-25 (citing *Kessman*

v. Myriad Genetics, Inc., No. 2:18-cv-00336-DAK, 2019 WL 11330363 at *9 (D. Utah Mar. 25, 2019)).

Under a corrective disclosure theory of loss causation, a plaintiff must identify a corrective disclosure that reveals the truth regarding the defendant's misrepresentations and "show that it was this revelation that caused the loss and not one of the [other] 'tangle of factors' that affect price," such as "changed economic circumstances, changed investor expectations, new industry-specific or firm-specific facts, conditions, or other events, which taken separately or together account for some or all of that lower price." *In re Williams Sec. Litig.*, 558 F.3d at 1137 (quoting *Dura Pharm.*, 544 U.S. at 342-43). "To be corrective, the disclosure need not precisely mirror the earlier misrepresentation, but it must at least relate back to the misrepresentation and not to some other negative information about the company." *Id*. at 1140.

Here, Plaintiffs' opposition memorandum identifies the corrective disclosure theory as a basis for finding that they have adequately pleaded loss causation in their amended complaint, but they do not explain how the amended complaint satisfies the requirements of that theory. Neither the amended complaint nor Plaintiffs' briefing identify a corrective disclosure that relates back to any of the purported misrepresentations challenged in the complaint.

Plaintiffs allege that it was Lipocine's November 2019 press release announcing that the FDA had issued a CRL rejecting the May 2019 NDA on the grounds that TLANDO's "efficacy trial did not meet the three secondary endpoints for maximal testosterone concentrations ('Cmax')" as the cause of the subsequent fall in Lipocine's stock price. (Am. Compl. at ¶¶ 94-96.) But Plaintiffs fail to explain how the November 2019 press release revealed that any of Defendants' purported misrepresentations were fraudulent. The only relevant information revealed by the

November 2019 press release was (1) that the FDA had issued a CRL regarding the May 2019 NDA and (2) that the FDA had identified TLANDO's failure to meet the FDA's secondary endpoints for Cmax as the reason for the CRL. But, as explained above, the fact that TLANDO had not met the FDA's secondary endpoint thresholds was disclosed by Defendants before and throughout the class period, both in press releases and in Lipocine's annual and quarterly reports. The revelation that TLANDO's secondary endpoints did not satisfy the FDA's standards could not have constituted a corrective disclosure when such information was publicly available through Lipocine's own disclosures.

Moreover, the amended complaint does not allege any facts to show that the fall in Lipocine's stock price following the November 2019 press release was attributable entirely, or even partially, to a revelation of Defendants' purported fraud, as opposed to the news that Lipocine's latest application for FDA approval of TLANDO had been denied, which was certainly negative information that would have impacted Lipocine's stock price. As the Supreme Court explained in *Dura Pharmaceuticals*, plaintiffs alleging loss causation must show that their loss is attributable to the disclosure of the fraud and not some other non-fraud related factor. 544 U.S. at 342-43. Plaintiffs' amended complaint does not identify any basis for making such a distinction.

Plaintiffs' materialization of risk theory fails for similar reasons. "Under a theory of materialization of a concealed risk, a plaintiff alleges loss causation by showing that the defendant's misrepresentation concealed a risk that caused a loss for the plaintiff when the risk materialized." *Nakkhumpun v. Taylor*, 782 F.3d 1142, 1154 (10th Cir. 2015). To plead loss causation on a materialization of a concealed risk theory, a plaintiff must allege that (1) "[t]he risk that materialized was within the zone of risk concealed by the misrepresentation (foreseeability)"

and (2) "[t]he materialization of the risk caused a negative impact on the value of the securities (causal link)." *Id*. To adequately plead either factor that is required to establish loss causation under a materialization of risk theory, a plaintiff must, necessarily, identify the risk that was allegedly concealed and then later materialized.

Here, Plaintiffs fail to clearly identify, either in the amended complaint or their briefing, what the risk was that was purportedly concealed by Defendants' alleged misrepresentations.

At times, Plaintiffs appear to claim that the risk that materialized and caused their losses was the FDA's issuance of a CRL based on TLANDO's failure to meet the FDA's secondary endpoint standards in response to the May 2019 NDA. If this is the risk that Plaintiffs rely on, however, their claims fail because Lipocine disclosed that risk throughout the class period. Each of Lipocine's annual and quarterly reports to the S.E.C. disclosed that the May 2018 CRL rejected Lipocine's prior NDA because of Lipocine's failure to meet the FDA's secondary endpoint thresholds and that the secondary endpoints were not met pursuant to the per day measure. Those same reports repeatedly disclosed that there was no guarantee that the FDA would ever approve TLANDO and stated that there was no assurance that the FDA would accept the May 2019 NDA. There are no allegations that Defendants ever guaranteed that the May 2019 NDA would be approved, or that any of Defendants' alleged misrepresentations implied such a guarantee. In short, Plaintiffs have not alleged any facts showing that the risk that the May 2019 NDA would not be approved was concealed by Defendants. Accordingly, a materialization of risk theory based on the risk that the May 2019 NDA would not be approved is not supported by the allegations in the amended complaint.

At other times, Plaintiffs appear to be asserting that the risk that materialized, and caused their losses, was the risk that the chances of FDA approval were lower than what was perceived by investors in light of Defendants' purported misrepresentations. The amended complaint alleges that Defendants' purported misrepresentations "created a false impression that the Cmax secondary endpoints were not a significant impediment to the FDA's approval of TLANDO," (Am. Compl. at ¶ 61) and that "the FDA was exceedingly unlikely to approve the TLANDO NDA given that the Company had failed to address the failure to meet the secondary endpoints" (*id*. at ¶¶ 73, 77, 79, 81, 87, 91, 93.) These allegations are consistent with a materialization of risk theory based on a concealed risk that the chances of NDA approval were lower than investors were led to believe.

Such a claim, in theory, could satisfy Plaintiffs' obligation to plead loss causation. For example, if the amended complaint alleged facts that showed that Defendants' misrepresentations led investors to believe that the chances of FDA approval were 70%, when the actual chances of approval were only 30%, then loss causation could be shown by alleging that the actual chances of FDA approval were eventually revealed and caused a fall in Lipocine's stock price. The amended complaint, however, alleges no such thing.

As discussed, the amended complaint points to the announcement of the November 2019 CRL as the event that caused Plaintiffs' losses. But the November 2019 CRL does not reveal any information regarding what the actual likelihood of FDA approval was before the May 2019 NDA was rejected. The amended complaint identifies no other disclosure that may have revealed to investors that they had overestimated the chances of FDA approval based on Defendants' purported misrepresentations. And it also fails to allege that Plaintiffs experienced any actual loss

based on such an unidentified disclosure. The issuance of the November 2019 CRL was not a materialization of the risk that investors had overestimated the prospects that the May 2019 NDA would be approved. Accordingly, the amended complaint also fails to adequately allege loss causation based on this theory.

The amended complaint's failure to allege facts sufficient to support any identified theory of loss causation is another, independent, basis for dismissing Plaintiffs' claims.

II. Section 20(a) Claim

Plaintiffs have also asserted a claim against Dr. Patel, as a person in control of Lipocine, under Section 20(a) of the Exchange Act. Section 20(a) provides that "[e]very person who, directly or indirectly, controls any person liable under any provision of [the Exchange Act] or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable." 15 U.S.C. § 78t(a). Thus, in order to establish control person liability under Section 20(a), a plaintiff must first establish that the "controlled person," in this case Lipocine, was primarily liable for a violation of the Exchange Act. *Adams v. Kinder-Morgan, Inc.*, 340 F.3d 1083, 1107 (10th Cir. 2003) ("[T]o state a prima facie case of control person liability, the plaintiff must establish (1) a primary violation of the securities laws and (2) 'control' over the primary violator by the alleged controlling person.") (citation omitted).

Because the court has held that Plaintiffs have failed to state a claim against Defendants for a violation of Section 10(b), there is no primary violation that can provide the basis for control person liability against Dr. Patel under Section 20(a). Plaintiffs' Section 20(a) claim is, therefore, dismissed as well.

Conclusion

For the reasons stated herein, the court GRANTS Defendants' motion to dismiss. The amended complaint is hereby DISMISSED WITH PREJUDICE.

DATED this 13th day of April, 2023.

BY THE COURT:

The Honorable Clark Waddoups
United States District Court Judge